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Impression 3D en chirurgie de la main

3D printing in hand surgery

Valérie Matter-Parrat, Philippe Liverneaux

Department of Hand Surgery, SOS hand, University Hospital of Strasbourg, FMTS, University of Strasbourg, Icube CNRS 7357, 1 avenue Molière, 67000 Strasbourg, France

Corresponding Author:

Liverneaux Philippe Hand Surgery Department, Strasbourg University Hospitals 1 avenue Molière, F-67000 Strasbourg, France Tel + 33 6 88 89 47 79 Philippe.liverneaux@chru-strasbourg.fr

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Philippe Liverneaux has a conflict of interest with Argomedical, Newclip Technics. None of the other authors have conflicts of interest.

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Abstract

While 3D printing in hand surgery is still in its infancy, it offers new avenues in research, teaching, and personalized medicine. For these reasons, some surgeons may want to jump on the bandwagon of this trendy technology. But we cannot forget that its superiority over conventional techniques has not been demonstrated. Surgeons who want to work with 3D printed objects must master their use and the entire manufacturing process, otherwise they risk becoming dependent on engineers and/or medical device companies.

Résumé

L'impression 3D en chirurgie de la main en est encore à un stade balbutiant. Certes, elle offre de nouvelles perspectives en matière de recherche, d'enseignement et de médecine personnalisée. Pour ces raisons, les chirurgiens doivent s'en emparer pour la faire progresser. Comme toutes les nouvelles technologies, elle fait l'objet actuellement d'un engouement par effet de mode. Il ne faut pas perdre de vue qu'elle n'a pas encore fait la preuve de sa supériorité par rapport aux techniques conventionnelles et que les chirurgiens doivent rester maîtres de l'ensemble de la chaîne de fabrication et d'utilisation au risque de devenir dépendants d'ingénieurs et/ou d'industriels.

Keywords: 3D printing; Stereolithography; SLA; Selective Laser Sintering; SLS; Binder Jetting; BJ; PolyJet; Fused Deposition Modeling; FDM

Mots-clés : Impression 3D ; Stéréolithographie ; SLA ; Frittage de poudre ; SLS ; Liage de poudre ; BJ ; PolyJet ; Dépôt de fil fondu ; FDM

1. Introduction

Various implants are used in hand surgery, whether for bone fixation or arthroplasty. For bone fixation, some of these implants require alignment guides or bone models [1]. For arthroplasty, others use resection instrumentation [2] and/or trials [3]. Traditionally, implants are manufactured using processes that involve removal (turning, milling, boring), deformation (forging, folding), fusion (fritting, molding) or assembly (soldering, gluing, bolting on) of materials.

In the ideal case, each implant will match the patient's anatomy. Given the economic constraints and manufacturing timelines, most implants are available as product lines comprising several sizes, shapes and sides. But in some cases, none of the available implants match the patient's anatomy. Under these conditions, if bone fixation is being performed, the surgeon modifies the shape of the implant, for example by bending it to match [4]. For an arthroplasty case, the surgeon may ask the implant manufacturer to design a custom implant [5].

 Fortunately, another option has emerged over the past 10 or so years—additive manufacturing (AM)—which is defined by the French Rapid Prototyping Association (AFPR) as a "material addition process consisting of manufacturing parts directly from a 3D digital model without the use of tools" [6]. Three-dimensional (3D) printing makes it possible to manufacture any object in a highly accurate manner, without any assembly or material waste. This object weighs less than one made with traditional methods. These implants or objects resulting from 3D imaging (by extension, a 3D object) are designed to precisely match a patient's specific anatomy. Currently, 3D instrumentation can be made at a healthcare facility [7], while 3D implants must be made by a medical device company, given the technical and regulatory constraints.

The aim of this review is to summarize the history of AM, describe the various 3D printing methods, study its applications in hand surgery and lastly, show how it can be used in a clinical case.

2. History

Three-dimensional printing was imagined by artists before its practicability was demonstrated by engineers and it was applied in medical fields.

Among these artists, Arthur C. Clarke—the author of "2001: A Space Odyssey" predicted in 1964 that one day, we would use a machine called "the replicator", to create objects as easily as we print books [8]. In 1972, Greg—a colleague of Hergé—had Professor Tournesol make a 3D photocopier coveted by Rastapopoulos to make copies of stolen pieces of art [9].

On the engineering side, the first patents about AM where filed in 1984 by Jean-Claude André, Olivier de Witte and Alain le Méhauté, who were working for the French company Cilas Alcatel™, while Charles Hull filed patents on stereolithography in the United States [10]. The first commercialized 3D printer was the SLA-1 in 1987 [11] and the first metal 3D printer (Direct Metal Laser Sintering) was introduced in 1994 [12]. In the medical domain, Mankovich reproduced one of the first anatomical models of the skull by stereolithography based on CT scan data in 1990 [13].

3. 3D printing methods

The process of 3D printing from medical images consists of five steps: 1) acquisition of medical image in DICOM format; 2) segmentation/conversion of the medical image; 3) preparation of image before printing; 4) 3D slicing/printing; 5) post-processing.

3.1. Acquisition of medical images in DICOM format

The first step consist in obtaining a 3D medical image from millimeter-level slices of the region of interest generated by CT scan or MRI. This image is always in Digital Imaging and Communications in Medicine (DICOM) format, which is the standard format for medical imaging files.

3.2. Segmentation/conversion of the medical image

The second step consists of making a segmentation/conversion of the medical image from DICOM format into STL (or stereolithography) file format. Other formats can be used, for example OBJ.

Segmentation, which is also called contouring, consists in manually selecting the bone tissue on the image using specific software. However, the segmentation is often not perfect, in part because some of the bone tissue may not have been selected, and in part because non-bone tissue may have also been selected. While automatic segmentation can be done using gray-level thresholds, the output is lower in quality than manual or semiautomated segmentation.

The conversion step consists of converting the segmented image into STL format using specific software. The mesh generated has varying levels of refinement and is composed of triangles oriented in space that make up a volume with a non-smooth surface. For this step, the same software can be used, either open source (Osirix® for Macintosh, 3D Slicer® for Windows and Linux, MeVisLab) or licensed (Mimics®, Magics®).

Online 3D printing services (for example, sculpteo.com) manage the slicing and optimization of STL or OBJ files submitted to them. This is a viable option, as it is cheaper than buying a 3D printer.

3.3. Preparation of medical image before printing

The third step consists of improving the STL image before printing. First, the remaining soft tissues are removed to obtain only bone tissue, then the bone surface is smoothed to achieve a realistic rendering, and lastly, the bone density is reduced to save on the quantity of consumables or "ink" to make printing faster.

During this step, open source (Blender®) or licensed (Mimics®, Magics®) 3D modeling software can be used. Note that for an annual cost of €11,000, Mimics® software (Materialise™) can be used to retrieve an image from a hospital's PACS (Picture Archiving and Communication System), segment/convert it and then prepare it for printing.

3.4. 3D slicing/printing

The fourth step consists of slicing/printing the prepared image. Slicing consist of cutting out the prepared image into multiple transverse digital layers. Printing consists of making a physical representation of the various 2D layers one-by-one to construct a 3D object. During this step, a software function called slicer is used that either comes with the 3D printer or is an add-on if the printer doesn't have it (Magics®, ReplicatorG®, etc.). Several AM processes exist (Table 1). The ones used most often in the context of bone surgery are described below.

3.4.1. Stereolithography

The stereolithography (SLA) process, one of the first introduced, uses the principles of photopolymerization [14]. The 2D layers are printed by movements of a laser beam. The third dimension is obtained by moving a platform containing the raw material (resin).

The printer consists of a bath on which the mobile platform sits (Fig. 1). The bath is filled with UV curable polymer resin. The platform is moved down over a distance equal to the thickness of one layer. A scraper goes back-and-forth on the resin surface to produce a flat, uniform surface [15]. A UV laser beam passes above the platform, which polymerizes the first layer of resin. The platform then descends over a distance equal to the thickness of the second layer. The same process is repeated to polymerize the second layer. The layers bind to each other through the same chemical process of surface polymerization [14]. The process is repeated with the subsequent layers until the complete 3D object is made. The 3D object is cleaned chemically with a solvent to remove excess, non-polymerized resin. UV post-processing is done to finalize the photopolymerization of the 3D object and to increase its mechanical strength. Mechanical post-processing is sometimes also done to remove a support that was used to hold up the unstable 3D object on the platform.

Among the advantages of SLA are that the surface of the 3D object is one of the best and this type of printer is one of the cheapest (starting at €1000). Among the drawbacks of

SLA are that the surface of the 3D object requires post-processing (sanding and support removal) and the size of the 3D object is limited by that of the printer.

3.4.2. Sintering of powders

The selective laser sintering (SLS) process uses the principle of agglomeration by localized fusion of a plastic or metal powder [16]. The 2D layers are printed by the movements of a laser beam. The third dimension is obtained by moving a platform containing the raw material (powder).

The printer consists of three aligned compartments (one central, two peripheral) with a mobile platform residing in each (Fig. 2). The first peripheral compartment is filled with plastic or metal powder. The platform of the first peripheral compartment is raised and that of the second central platform is lowered over a distance equal to the thickness of one layer. A roller gathers and transfers the powder needed from the first peripheral compartment to the central compartment and then the excess powder to the second peripheral compartment. A $CO₂$ laser beam produces heat by passing above the central platform, which fuses the first layer of powder. The same process is repeated to fuse the second layer, but in the reverse direction. The platform of the second peripheral compartment is raised and those of the central compartment and first peripheral compartments are lowered over a distance equal to the thickness of one layer. A roller gathers the powder needed from the second peripheral compartment to the central compartment and then the excess powder to the first peripheral compartment. The process is repeated with the subsequent layers until the complete 3D object is made. Post-processing consists of removing excess powder using compressed air and then polishing the 3D object by grit blasting. The appearance can be improved by adding surface treatments such as paint or lacquer [17].

Among the advantages of SLS are that a large variety of raw materials can be used (polymer, stainless steel, titanium, alloys) and that the mechanical properties are reliable (mechanically and chemically resistant to temperature changes). There are no shape constraints as no support is needed during the process. Among the drawbacks of SLS are

that the surface of the object is porous and the manufacturing time is long because of the printer's required heating time and the 3D object's cooling time.

3.4.3. Binder jetting

The binder jetting (BJ) process uses the principle of powder agglomeration by a binder [18]. The 2D layers are printed by movements of the printing head containing a binder. The third dimension is obtained by moving a platform containing the raw material (powder).

The printer has two compartments (donor and receiver), with each having a moving platform (Fig. 3). The donor compartment is filled with various powders (ceramic, metal, elastomer, plastic, sand, sugar). The platform in the donor compartment is raised and that of the receiver compartment is lowered over a distance equal to the thickness of one layer. A roller gathers the powder needed from the donor compartment and brings it to the receiver compartment. This powder is then solidified by the deposition of a colored binder to form the first layer, like an ink-based printer head. The same process is repeated to bind the second layer, and so on, until the complete 3D object is made. Post-processing consists of first removing the excess powder and then applying a substance such as glue (for ceramics) or bronze (for metals) to improve the mechanical properties [19].

Among the advantages of BJ are that any 3D object can be printed in any color since the 3D printer comes with four primary color cartridges. There are no shape constraints as no support is needed during the process. Among the drawbacks of BJ are that the 3D object has low mechanical strength.

3.4.4. PolyJet process

The Polyjet process uses the same principles as inkjet printing [20]. The 2D layers are printed by movement of the printing heads containing the raw material (drops) and UV light. The third dimension is obtained by moving a platform on which the raw material is deposited.

The printer consists of several printing heads and a mobile platform (Fig. 4). Each printing head is filled with different types of liquid resin (transparent, rigid or opaque

materials, or different types of rubber) [21]. The platform is moved down over a distance equal to the thickness of one layer. Several printing heads, each with many dozens of nozzles, project microdrops on the platform. A UV light polymerizes the raw material to form the first layer. The same process is repeated to bind the second layer, and so on, until the complete 3D object is made. In some cases, the 3D object is not stable on the platform, thus must be held by a support that is printed simultaneously. In this case, post-processing is needed to remove this support, either by mechanical separation or chemical dissolving.

Among the advantages of the Polyjet process are that hundreds of raw materials can be used, sometimes simultaneously, which have various colors and textures. Among its drawbacks are that the 3D object requires post-processing, i.e. support removal.

3.4.5. Fused deposition modeling

The fused deposition modeling (FDM) process uses the principle of thermal fusion of a thermoplastic filament. The 2D layers are printed by movements of an extrusion head containing the raw material (heated thermoplastic filament). The third dimension is obtained by moving a platform on which the raw material is deposited.

The printer is made up of a reservoir containing the thermoplastic filament on a spool, connected to the extrusion head (Fig. 5). The extrusion head heats the filament to melt it and then moves around the platform to make the first layer. The platform is moved down over a distance equal to the thickness of one layer. The same process is repeated to form the subsequent layers until the complete 3D object is made. The resulting 3D object requires post-processing for support removal.

Among the advantages of the FDM process are that it is one of the newest and least costly methods, and the mechanical properties of the 3D object are equal to injected thermoplastic parts. The density of the parts can be reduced, which accelerates production and results in a lighter 3D object [22]. Among the drawbacks of FDM are that the final rendering of the 3D object is inferior to that of other techniques and the object's size is limited

by the size of the printer. Post-processing involves removing the support holding the 3D object.

3.5. Post-processing

Post-processing, which consists of finalizing the 3D printed object, consists of several options, depending on the printing techniques used (Table 1). This may include removing excess material, increasing the mechanical strength of the 3D object, removing the support and improving the object's appearance. Removing excess material can be done using a chemical solvent (SLA) or compressed air (SLS, powder binding). Increasing the 3D object's mechanical strength can make use of surface polymerization (SLA) or applying glue to ceramics / bronze to metals (powder binding). Removing the support required during the manufacturing of an unstable 3D object must be done by deburring (SLA, Polyjet, FDM) or by chemical dissolution (FDM). The object's appearance can be improved by polishing using bead blasting (SLS) or by spray painting or lacquering (SLA, SLS, powder binding, FDM) [23].

4. Applications

The applications of 3D objects in surgery are: 1) research, 2) training, 3) preoperative planning, 4) manufacturing of intraoperative cutting guides, 5) manufacturing of implants, 6) manufacturing of splints.

4.1. Research

The 3D object can be used during biomechanical studies. For example, 3D printing can be used to make bone models that mimic the characteristics of human bone and can be used during biomechanical studies [24], especially comparisons of different bone fixation methods [25]. Among the future applications are regenerative medicine with bioprinting of stem cells on implants and bone matrix for osteotomies [26], like the organ regeneration described not long ago [27,28].

4.2. Training

While 3D objects cannot replace bed-side training with patients or practical courses in the anatomy laboratory, they can accelerate the theoretical and practical learning curve.

To our knowledge, no studies with 3D objects have been done in the context of theoretical learning for hand surgery. The initial studies were done in general osteology [29]. Since then, several randomized studies have shown better results on exams and greater satisfaction of medical students for learning of anatomy [30], osteology [31] and traumatology [32].

 From a practical learning point of view, the first trial with 3D objects in hand surgery was done on distal radius fractures with a surgical simulator [33] (Fig. 6). A randomized study showed improved distal radius shortening on fresh cadavers in surgical trainees using Wristsim® 3D objects versus Sawbones® [34].

4.3. Preoperative planning

Three-dimensional printing can also be used to better understand a complex fracture, malunion or nonunion, to practice its reduction and/or fixation, or even to size the bone graft. Some authors have printed complex scaphoid [35] or distal radius [36] fractures to better evaluate the fracture line, displacement and stability.

Given that the range of fracture fixation implants has expanded to match various anatomies, 3D printing has been used to select which plate best matches the fracture pattern [37]. It has also been shown that if we carry out preoperative simulation before fixing distal radius fractures, the operative time, blood loss and x-ray dose are significantly reduced [38].

Clinically, there are instances where no plate perfectly matches the patient's anatomy. In this situation, the surgeon bends the plate extemporaneously, with a risk of errors and longer operative time. Three-dimensional printing can be used to perform this bending preoperatively. The plate is then sterilized before the procedure [39].

 Instead of using approximative methods [40], some surgical teams use 3D printing to determine the extent of bone resection for a nonunion case [41] or the shape and size of the graft to harvest [42,43]. We will discuss later on the possibility of printing custom implants.

4.4. Intraoperative cutting guides

Three-dimensional printing can be applied intraoperatively for the fixation or correction of a malunion.

Some authors have described making 3D printed cutting guides for the fixation of fractures or for osteotomy following by fixation of scaphoid nonunions. When working with fractures, an external guide in the shape of a rigid glove can be used to fix the scaphoid percutaneously on the first attempt [44]. When working with nonunions, one internal guide is used for the osteotomy of the malunion site, and the second internal guide used to reduce the fragments before screw fixation [45]. But these guides have a major drawback—the need for a wider surgical approach.

Other authors have described 3D printed bone cutting guides and plate positioning guides to help with making corrective osteotomy cuts for malunion cases. Cutting guides have been developed for the diaphysis [46-48] (Fig. 7) and the metaphysis [49-53], or even the epiphysis when the joint was involved [54]. Plate positioning guides have been developed to act as ramps to improve the positioning of the plate and screws [53]. Lastly, a metaanalysis of all the studies done with preoperative 3D planning for distal radius fractures collected 68 cases in 15 published articles, of which 10 used 3D printed cutting guides. The complication rate (16%) was not compared to that of standard techniques. Certain complications could not be attributed to use of the guides (rupture of extensor pollicis longus, material overhang) while others were evidence of their failure (disassembly, persistent distal radioulnar subluxation) [55].

4.5. Implants

Various types of implants can be made by 3D printing: fracture fixation plates, bone substitutes and arthroplasty components.

The fracture fixation plates printed in 3D closely match the patient's anatomy. The mechanical and geometric parameters (number and location of screw holes, shape and slope of plate) can be modified. A biomechanical study showed that the strength of a 3D printed plate produced by sintering of a titanium alloy powder was higher than that of standard plates [56].

Hand and wrist arthroplasty implants printed in 3D closely match the patient's anatomy. Some authors have made implants for tumor resection in the distal radius [57], the scaphoid [58], lunate [59] and even a phalanx [60]. Most were designed for palliative indications (giant cell tumors, Kienböck's disease).

A case report on correction of distal radius malunion pushed the boundaries of 3D printing by using this technology to make the cutting and fixation guides (polyamide), fixation plate (titanium) and bone substitute shaped as wedge for the osteotomy site (porous titanium) [50].

4.6. Splints

Splints and braces can be made by 3D printing that perfectly match the patient's anatomy and pathology [61]. Studies have demonstrated the effectiveness of 3D-printed splints for treating fractures and finger deformities. They improve the patient's comfort and satisfaction as they are light, breathable and waterproof [62-64]. To go further, some authors have developed lower cost myoelectric hand prosthetic with 3D printing that have a realistic appearance and allow grasping [65-68]. Some of these prosthetics are available on open source for local manufacturing [69].

5. Case report

We wanted to provide a real world example of how 3D printed objects can be used in the context of radius osteotomy and its application on a clinical case.

Several steps are involved before a 3D printed object can be used in surgery. The first consists of making the indication for complex osteotomy to correct distal radius malunion during the surgical consultation. A CT scan of the entire forearm on the injured and health contralateral sides must be done using the protocol set out by the manufacturer. The images are placed on a shared server that the company can use to make a 3D reconstruction of the skeleton. The company then provides a virtual 3D simulation of the osteotomy, type of fixation and cutting instrumentation. The surgeon can validate these elements as configured or propose modifications to the 3D simulation. Next, the company uses their 3D printing technology to make several models of the distal radius reconstruction, fixation devices, cutting guides and potential model graft for the surgeon to practice on before the procedure is performed on the patient. Once the surgeon validates these elements, all of the 3D objects to be used during the procedure, along with the preoperative plan, are sent to the surgeon. The final steps consist of performing the surgical procedure on the patient using the sterile materials.

Our clinical case involved a 16-year-old, right-handed male with a fracture of the left distal radius that was treated at another hospital by intrafocal pinning. He consulted us 3 years later with symptoms of ulnocarpal impingement. We carried out preoperative 3D planning and used 3D-printed cutting guides intraoperatively (Fig. 8). While a graft had been planned, the surgeon decided not to use it during the procedure. The patient's pain during wrist deviation was resolved, and he was able to resume all of his activities.

However, this procedure with 3D printed elements had several drawbacks. The first is that the procedure required a larger surgical approach than usual, in order to properly apply the guide on the bone. The second was that it was not easy to insert the saw blade into the specified slot because of the space taken up by the K-wires. The third was that a glitch with the design of the 3D guides led to the manufacturing of an object with only three distal holes whereas the plate had four holes. The fourth was that the 3D technology did not allow the plate to be applied perfectly on the anterior cortex of the radial epiphysis in this patient.

Overall, in this specific case, despite the patient having a good clinical outcome, the surgeon was not entirely satisfied with his experience using 3D printed objects.

6. Conclusion

While 3D printing in hand surgery is still in its infancy, it offers new avenues in research, teaching, and personalized medicine. For these reasons, some surgeons may want to jump on the bandwagon of this trendy technology. But we cannot forget that its superiority over conventional techniques has not been demonstrated. Surgeons who want to work with 3D printed objects must master their use and the entire manufacturing process, otherwise they risk becoming dependent on engineers and/or medical device companies.

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Figure legends

Fig. 1. 3D printer for stereolithography from https://www.cadimensions.com/blog/sla-vspolyjet-need-know/

Fig. 2. 3D printer for selective laser sintering from

https://www.britannica.com/technology/selective-laser-sintering/media/1800296/167341

Fig. 3. 3D printer for binder jetting from https://www.3dnatives.com/impression-3d-liagepoudre-08062016/

Fig. 4. 3D printer for raw material projection (Polyjet) from

https://www.cadimensions.com/blog/sla-vs-polyjet-need-know/

Fig. 5. 3D printer for fused deposition modeling from

http://www.custompartnet.com/wu/fused-deposition-modeling

Fig. 6. Artificial 3D simulator (Wristsim®) for training on volar plate fixation of distal radius fractures. It consists of a right upper limb and a cartridge containing a fracture that is introduced in the limb. From Lazarus et al. [33].

Fig. 7. Application of a 3D cutting guide for a complex osteotomy of the radius shaft.

Fig. 8a. Clinical case of corrective osteotomy for distal radius malunion. Preoperative planning AP view (top) – the black line is used to calculate the ulnar variance. Lateral view (bottom) – the black line is used to calculate the radial slope. Left to right: preoperative radiograph, preoperative 3D reconstruction, 3D simulation of the osteotomy, 3D reconstruction of the healthy contralateral side.

Fig. 8b. Planning of the surgical technique: Application of the cutting guide (A). Verification by fluoroscopy (B). Drilling of screw holes (C). Osteotomy performed with oscillating saw through the designated slot (D). Application of distractor (E). Oscillating saw used to cut bone graft using designated instrumentation (F). Graft after being cut to size (G). Application of graft into osteotomy (H). Application of plate and locking screws into the drilled holes (I). Fig. 8c Intraoperative radiographs

Fig. 8d AP view (upper), lateral view (lower), preoperative view (left side) and 6 months postoperative view (right side)

Fig. 8e Clinical outcomes at 6 months postoperative: upper images show supination, pronation, radial deviation; lower images show extension, flexion, ulnar deviation

Table titles

Table 1. Features of the various types of 3D printing methods

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Y: yes; *N*: no; *SLA*: stereolithography; *SLS*: selective laser sintering; *FDM*: fused deposition modeling